

Concepts of animal well-being and predicting the impact of procedures on experimental animals.

DJ MELLOR and CSW REID

Department of Physiology and Anatomy, Massey University
Palmerston North, New Zealand.

ABSTRACT

1. We argue that:
 - in their application to non-human animals, 'welfare' and 'well-being' are interchangeable words; and that
 - good welfare/well-being is the state of being manifest in an animal when its nutritional, environmental, health, behavioural and mental needs are met.
2. These latter are essentially the 'five freedoms' formulated by the Farm Animal Welfare Council of the United Kingdom.
3. Using the five freedoms as a basis, we have developed a system for assessing the impact of a proposed animal experiment or usage. The freedoms are now transformed into 'domains of potential compromise' and are redefined better to emphasise the extent of welfare compromise rather than the ideal of absence of compromise. Domain 1 is Thirst/hunger/malnutrition, 2 is Environmental challenge, 3 is Disease/injury/functional impairment, 4 is Behavioural/interactive restriction, and domain 5 is Anxiety/fear/pain/distress. A proposal would be examined systematically in all domains, and the degree of compromise in each rated on a 5-step non-numerical scale - O, A, B, C, X. Anxiety/fear/pain/distress arising from compromise in domains 1-4 would be cumulated into domain 5. The overall rating would commonly be that given to domain 5, but if this were low or unknown, it would be given to the highest rating in the other domains.
4. The proposer would be required to present to the institutional Animal Ethics Committee his/her assessment of the impact of a proposed experiment on the animals involved, together with an appropriate justification for the work and a cost-benefit analysis.
5. The extent of the justification required for a proposal would be directly related to the severity of compromise expected, being low for grade O and very high for grade X.
6. The cost-benefit decision would be based on the balance between the expected severity of welfare compromise and the expected benefits set out in the justification.
7. The major advantage of this system for assessing the impact on welfare is that it encourages systematic consideration of *all* sources of possible compromise. Such wider consideration would allow more accurate assessment of the severity of impact and thereby would improve the validity and efficiency of cost-benefit analyses.
8. The philosophical background to our approach is outlined, graded examples of welfare compromise are given and ethical and practical implications of using the system are discussed.
9. We also set out what we consider to be the ethical and practical responsibilities of the researcher to the animals, and to his/her assistants. The conscientiousness and comprehensiveness of the assessments of welfare compromise and the actions taken to minimise it are measures of the researcher's acceptance of ethical responsibility for all features of each experiment which affect the animals adversely.

INTRODUCTION

As judged by the extent to which we can now manipulate or control body processes effectively, the pursuit of animal-based science has been very successful and holds great promise for further advances in the future. Animal-based science includes all fundamental or applied biologies concerned with humans and other animals, such as:

- biologies dealing with human recreation or performance
- biomedical and veterinary preventive or therapeutic interventions
- food and fibre production by domesticated or wild animals
- the mechanisms underlying normal body function and behaviour patterns
- the conservation and management of endangered or exotic species
- the eradication or control of pest animals.

Despite its demonstrable success during this century animal-based science - in common with science in general - has been largely two-dimensional. The first dimension resides in the *acquisition* of knowledge and the second dimension in the *application* of that knowledge for human ends. There is, however, a third dimension (Figure 1). It is the *ethical implications* of the modes of acquisition and use of scientific knowledge. Although this third dimension has in fact been an implicit part of the conduct of science, it has been commonly ignored by scientists who mostly considered ethical issues to be beyond the realm of their legitimate concern. As a consequence evaluations of ethical issues have effectively remained outside science, being left mainly to philosophers and theologians to pursue. That is as true of animal-based science in particular as it is of science in general.

We hold the view that it is only by the explicit inclusion of this ethical third dimension in our pursuit and application of scientific knowledge that particular sciences (and their practitioners) will be able to retain vitality, credibility and relevance to the times in which we live. That is especially true for animal-based science at present. It is currently subject to radical, sophisticated and fundamental questioning of the ethical justifications for most of its activities involving other animals (see Singer, 1990; Sapontzis, 1990; Rollin, 1990), a questioning which reflects contemporary concerns about animal welfare, especially the welfare of animals used in agriculture and science. That questioning, which we believe to be both necessary and beneficial for the advancement of all animal-based science, is largely responsible for the existence of ANZCCART and the interest generated by the present conference on the well-being of animals in the research environment.

Animal Welfare Science - the science concerned with the acquisition and application of the knowledge required to define, maintain, restore and promote animal welfare (Mellor, 1992) - provides an excellent vehicle for demonstrating, exploring and developing aspects of the ethical third dimension of animal-based science, as illustrated by some recent publications (Rollin and Kesel, 1990; Tannenbaum, 1991; Kuchel, Rose and Burrell, 1992; Porter, 1992; Sandoe and Simonsen, 1992; Stamp Dawkins and Gosling, 1992). The intersection of science and ethics in the animal welfare arena therefore offers opportunities both to advance the interests of animals and to demonstrate the importance of introducing consideration of values if the continuing credibility of animal-based science is to be safeguarded.

HEALTH-ILLNESS CONTINUUM AND WELFARE-SUFFERING CONTINUUM

The state of being of an animal, whether human or not, varies over a range. *Good health*, characterised by high levels of both affective and functional competence, is located at one end of this range, and *extreme illness*, characterised by severe affective and functional compromise with death imminent, is located at the other end (Dunn, 1961). Between these two - good health and extreme illness - lies a continuum of states (Figure 2a). Those states are usually

described either in terms of the extent of movement *away from* good health, i.e. the degrees of loss of good health, or in terms of the extent of movement *towards* good health away from states of compromised health, i.e. the degrees of regained good health (Figure 2b). Clearly our usual focus is on good health as such, the preservation of good health or the restoration of good health in all its dimensions.

To emphasise this point it is worth noting that the same continuum of states can be described with semantic consistency, but less appeal, by using extreme illness as our reference point. Thus, we could speak in terms of 'degrees of compromise to extreme illness' to indicate stages of what we would usually refer to as 'recovery', or about the 'acquisition of extreme illness' to denote the appearance of very severe compromise (Figure 2c). The low appeal of this approach arises because it has the unsatisfying outcome of being expressed in terms which focus on the opposite of our implicit or explicit desire to have and retain good health. Hence the state of good health would need to be expressed - absurdly - in terms of having or retaining 'totally nullified illness'.

An important point underlies this apparent absurdity. Health is defined, implicitly or explicitly, by what it is not, by its opposite. So too is illness. We cannot know what we mean by health without implicit or explicit reference to illness. We cannot know what we mean by illness without implicit or explicit reference to health. Furthermore, as *absolute* concepts the two - good health and extreme illness - cancel each other out. Thus, health and illness are mutually defining and mutually exclusive concepts.

As indicated above we also recognise different *degrees* of health and illness. A corollary of the above reasoning is that within the health-illness continuum representing the states between good health and extreme illness, as health declines illness must increase, and conversely, as illness decreases health must increase (Figure 3). That is supported by observation. For instance, in cases of mild illness impairment is usually confined to one or only a few areas of the body, leaving the rest of it largely unaffected, whereas marked debility can involve compromise to many body systems resulting from widespread primary impairment or from major primary impairment of one vital system.

Thus, at different times an animal, be it human or not, exhibits different balances between good health and extreme illness, those balances being represented by different positions within the health-illness continuum.

The purpose of the above analysis is to indicate that, as with the term 'health', our present use of the term 'welfare' (or 'well-being') carries with it

- (1) reference to that state as an absolute juxtaposed implicitly or explicitly with its opposite of, say, 'suffering' (Figure 4a),
- (2) recognition of a continuum of states which lies between the two opposite extremes (Figure 4a),
- (3) a mode of expression regarding that continuum which indicates our inherent bias towards or preference for one of its extremes (i.e. welfare) (Figure 4b), and
- (4) characterisation of that continuum such that as welfare declines suffering increases, and vice versa (Figure 4c).

Different features of the welfare-suffering continuum will be considered below.

WELFARE AND WELL-BEING

We regard the terms 'welfare' and 'well-being' as interchangeable - they both refer to good states of being, physical and mental, of animals. [*Welfare*: well-being, happiness, health, prosperity, etc. *Well-being*: state of being well, healthy, contented, etc. (Concise Oxford English Dictionary - 8th Ed.)] A current distinction made between the two (Fraser, 1992), wherein well-being refers to endogenous states of being within an animal and welfare refers to human interventions designed to promote good well-being, makes the use of these terms unnecessarily complicated and potentially confusing, especially for lay people. That practice seems to confer little benefit, especially as precise reference to 'human promotion of welfare'

or to 'welfare promotion' avoids confusion and at the same time retains a useful synonym for a good state of being. Our consistent use of the terms welfare and well-being as synonyms in this paper reflects this view.

WELFARE AND SUFFERING

When applied to animals, including humans, the term 'welfare' (or 'well-being') usually denotes an absence of 'suffering' or an absence of what might be argued are major components of suffering - i.e. anxiety, fear, pain and distress. That word usage seems to be especially prevalent in the research context where our objective is to minimise the cost to other animals of their use in experiments. Suffering of almost any sort is taken to represent an unpleasant, undesired state of being which is the outcome of the impact on the animal of noxious stimuli, whatever their origin or type. A wide variety of circumstances can lead to suffering and suffering takes many forms. Suffering can be acute or chronic, it or its components can have a range of intensities, it can manifest predominantly as anxiety or fear or pain or distress or different combinations of these phenomena, and the body responses can be mainly physical, largely mental or both physical and mental.

The diversity of both the sources and expressions of suffering, and their apparent quantifiability, help explain the common use of levels of suffering as a major criterion for attempts to assess the acceptability to us, on the basis of the anticipated cost to the animals, of their use in experiments (Bateson, 1986; Fraser, 1990; CCAC, 1991; Porter, 1992; Reid and Mellor, 1993). Nevertheless there is a danger that with our focus largely on suffering we could overlook a broader view of welfare (or well-being) which may be more informative and safeguard more effectively the interests of the animals in the experimental environment. It would be useful therefore to devise a system which aids broad consideration of all potential sources of suffering in order to reduce the risk of making significant omissions when evaluating the possible untoward consequences for the animals of proposed experiments. Such breadth is included in the concept of the 'five freedoms' formulated by the Farm Animal Welfare Council (FAWC, 1992) of the United Kingdom (Table 1). The five freedoms not only include specific reference to distress, fear and pain, but also highlight a range of factors which individually or collectively can lead to suffering. They are thirst, hunger and malnutrition, environmental discomfort, injury and disease, and thwarted behavioural expression. We consider that with some recasting the five freedoms could form the basis of a system for evaluating more comprehensively the ethical cost of experiments.

Although so far in this section we have emphasised evaluations of suffering, use of the five freedoms clearly allows simultaneous assessments of major dimensions of welfare. Two important consequences follow. First, a more comprehensive description of good welfare/well-being can be taken to include states of being which are manifest when the nutritional, environmental, health, behavioural and mental needs of the animals are satisfied. Secondly, a more exact definition of the *actual* state of welfare of an animal becomes possible by reference to the extent of compromise of those needs.

SENTIENCE AND CONSCIOUSNESS

There are two preconditions of both welfare and suffering which are of significance in the research environment. They are 'sentience' and 'consciousness'. Their significance is easier to comprehend by dealing with suffering first. It is axiomatic that without sentience there can be no feeling by the senses and without consciousness sentient animals cannot suffer. It follows that sentience and consciousness are also preconditions of welfare, because without them there can be no perception of states of faring well or of states without suffering. Accordingly, *in these terms* the welfare of non-sentient animals cannot be compromised because they are incapable of suffering. The same applies to sentient animals while they are unconscious, but clearly in that case welfare can be compromised before consciousness is lost and/or when or if consciousness returns. Animals must therefore have the capacity to suffer - through both sentience and consciousness - before it is possible for their welfare (or well-being) to be compromised.

These arguments are quite separate from any theoretical or practical difficulties we might encounter when attempting to determine which animals are and are not sentient, whether or not there are different levels of sentience, and which animals do and do not exhibit consciousness (Rollin, 1990; Porter, 1992).

WELFARE COMPROMISE IN RESEARCH

Although in some cases experiments involve very little intrusion into an animal's usual mode of living (e.g. benign nutritional trials or behavioural observations in the field), most research on animals involves erosion, to a lesser or greater extent, of one or more of the five freedoms. Accordingly the ideal of the five freedoms as goals for achieving good animal welfare on farms and elsewhere may be seen as inevitably compromised to some degree by the very nature of some, probably most, uses of animals in research. Defining what we mean by the term animal welfare (or well-being) as it applies in the research environment therefore needs to refer not so much to how good the welfare of research animals is, but more to how much their welfare is compromised. That emphasis highlights two ethical duties which are noted as major objectives of ANZCCART: (1) our duty to minimise the extent of welfare compromise to experimental animals and (2) our duty to maximise the benefits, however conceived, of animal-based research. Having recognised the first of those duties, we are faced with determining what we consider to be acceptable and unacceptable levels of welfare compromise, and that in its turn depends to some extent on how we seek to satisfy the second duty of maximising the benefits of animal-based research.

The acceptability of any welfare compromise will depend on a cost-benefit analysis which, if it is to be credible, must involve a *comprehensive* assessment of the negative impact of the experiments on the animals. In such cost-benefit analyses the emphasis we give the interests of the animals compared to that accorded the anticipated benefits of the work will reveal our underlying ethical position regarding our use of other animals for human purposes. In recent years that emphasis has shifted towards the animals and away from our purposes in using them. Examples of ethical positions which embody an asymmetry favouring the interests of the research animals themselves include the following: a commitment to minimising the debt we owe animals for their contributions to our quality of life (Mellor, 1988); a commitment to a 'Schweitzerian' ideal of avoiding harming animals whenever possible, leading to a restraining tension between that ideal and the perceived need to use some research animals for the wider benefit of humans and/or other animals (Porter, 1992); a commitment, at the very least, to maximise the interests of other animals which continue to be used in invasive research during a hoped for and actively promoted transition to the eventual complete disappearance of such animal use (Rollin, 1990).

Systems for determining different levels of welfare (or well-being) are an important aid to these deliberations (e.g. Fraser, 1990; CCAC, 1991; Reid and Mellor, 1993). If different levels of welfare could not be identified, we could not grade the extent of welfare compromise, nor conduct a cost-benefit analysis of particular research proposals, and nor could we act to improve the welfare (or well-being) of animals used for research or for other purposes. Presented below for your consideration is a system, based broadly on the principles embodied in the five freedoms, designed to assist with these endeavours.

GRADING WELFARE COMPROMISE

There are two main features of the grading system we propose. They are (1) five domains of potential welfare compromise and (2) a severity scale applied to each domain.

Domains of Potential Welfare Compromise

The grading system highlights *five overlapping domains of welfare*, expressed not as freedoms but in terms which emphasise welfare compromise (Figure 5). The welfare compromise, if any, caused by a particular experiment may occur in one or more of these five domains, which are:

Domain 1: Thirst/hunger/malnutrition

- Domain 2: Environmental challenge
- Domain 3: Disease/injury/functional impairment
- Domain 4: Behavioural/interactive restriction
- Domain 5: Anxiety/fear/pain/distress.

Reference to these five domains can help us to assess and then minimise untoward consequences of experiments on animals in three main ways. *First*, they draw attention to the wide range of general needs animals have and to our duty to ensure as far as is practicable that those needs are met throughout the experiment, from the time the animals are acquired to the time they are disposed of, alive or dead, at the end of the experiment. *Secondly*, they indicate areas where welfare compromise can occur which are not the primary focus of the experiment. Thus, by reminding us not to concentrate exclusively on the particulars of a proposed experimental procedure they help us to broaden our awareness and thereby to avoid overlooking related areas where compromise may occur as well. *Thirdly*, they provide a basis for assessing the extent of compromise in the welfare domain(s) which is(are) the primary focus of the experiment.

The following important interactions between the five domains should be noted (Figure 5).

1. Compromise in the first four domains (thirst/hunger/malnutrition; environmental challenge; disease/injury/functional impairment; behavioural/interactive restriction) will usually be registered in welfare terms in the fifth domain (anxiety/fear/pain/distress) which represents the components of suffering.
2. Although anxiety/fear/pain/distress, if they occur, would usually be a product of manipulations directed at the other four domains (as just stated), anxiety/fear/pain/distress can themselves be the primary focus of some experiments.
3. The final grading of welfare compromise would therefore usually be done by reference to the intensities and durations of anxiety/fear/pain/distress as likely outcomes of manipulations.
4. In cases where the intensities and durations of anxiety/fear/pain/distress caused by particular manipulations are not known or cannot be evaluated, the grading of compromise in the known domain(s) would be used to make a final assessment.

Severity Scale

The grading system also employs a *severity scale* to help assess the degrees of compromise within each of the five domains of welfare. The scale is not numerical. That avoids the apparent precision of arithmetic assessments whereby arbitrary numerical thresholds and manipulations can be used as substitutes for reasoned judgement (Reid and Mellor, 1993).

The severity scale consists of five grades - O, A, B, C and X - representing increasingly severe compromise. By aiding comprehensive assessments of the degrees of intrusiveness of proposed experiments, the scale is designed to help estimate the different levels of the associated ethical cost (see below).

The grading system as a whole is presented in Table 2. In it we have attempted to characterise the severity scale, descriptively and with examples, for each of the five domains of welfare. We see this as a provisional attempt - not a final system - which with feedback from others could be developed further. Terms such as 'minor', 'moderate', 'marked' and 'severe' purposely have not been defined - it is for the experimenter to determine their meaning in the particular context of each procedure. Furthermore, the examples presented are not exhaustive, they are illustrative. Nor are the examples definitive - we expect that the grading of some or many of them is likely to initiate debate. That is to be encouraged because an important purpose of the system is to stimulate thought about the severity of different experiments. Finally, the grading assigned to many procedures is likely to change as our understanding advances. The grading of each experiment should therefore always be seen as provisional.

USING THE GRADING SYSTEM

Each Severity Grade Must Reflect the State of the Animal at the Time of Maximum Impact

When assigning a severity grade in each of the five domains of potential welfare compromise, the grade must refer to the summed impacts of both the initial state of the animal and the induced effect of the experimental procedure, not to the induced effect alone. Two examples serve to illustrate this distinction.

(1) With studies of diseases as they occur spontaneously, it might be argued that the researcher did not cause the disease and therefore that the degree of intrusiveness assigned to the experiment should refer only to the effects of what the researcher does to study such diseases. This would result in the grading of experimental studies of spontaneous diseases often being less severe than the grading of the same diseases reproduced for study in the laboratory.

(2) By the same reasoning, studies on the farm of pain/distress caused by routine tissue removals for husbandry purposes (e.g. castration, tailing, dehorning) which are conducted without anaesthesia as part of the usual schedule of farm activities, would be assigned lower severity ratings than would laboratory studies of the same procedures conducted on animals which would otherwise not have been so treated.

Such reasoning neglects our ethical responsibility as custodians of the animals in our control to *intervene* when that is necessary and possible. The act of experimenting requires some form of access to the animals under study, where ever they may be located, and that provides the *opportunity* to intervene to treat the treatable, to palliate suffering or, as a final option, to euthanase severely compromised animals. If we choose not to intervene in such ways in order to achieve particular experimental objectives, our choice may be seen as equivalent to the act of our creating the entire conditions of the experiment ourselves. Accordingly, the grading of the degrees of welfare compromise during an experiment should not be affected by whether the phenomena under study have been created for study in the laboratory or have arisen spontaneously (e.g. diseases states) or during other common uses of animals (e.g. husbandry tissue removals).

The question arises as to whether there are any circumstances where the initial condition of the animal can be given less prominence and the *induced* effects of a procedure used as the primary basis for a grading. We think not.

It is important to make a clear distinction between the full extent of welfare compromise experienced by the animals under study and the reasons for studying the conditions which produce that compromise. The former is what is graded in the five domains of potential welfare compromise. The latter represents the justification for the study. However, that justification - which could include attempts to reduce the incidence of spontaneously occurring diseases or a desire to minimise the pain/distress of the routine husbandry procedures applied to farm animals - might not need to be as strong when studying 'pre-existing' states compared to that required if the same states were reproduced for study in the laboratory.

Each Experiment Must be Graded in All Five Domains of Potential Welfare Compromise

The overall grading of an experiment would usually be that assigned to the components of suffering (anxiety, fear, pain, distress) - the fifth domain. However, the combined use of all five domains of potential welfare compromise is necessary to help ensure that all factors which can contribute to suffering of different kinds have been assessed. When assessing compromise in each domain care must be taken to avoid inclusion of compromise to the

features of welfare dealt with in the other domains. The greatest anticipated compromise should be used when assigning the grade *in each domain*. When compromise in two or more domains contributes to suffering, assigning an appropriately higher grade to the area of anxiety/fear/pain/distress should be considered. The process of determining the overall grade is illustrated by the following five examples. The first shows that in the absence of suffering the highest grade in one of the other areas becomes the overall grade. In the next three examples the overall grade is the same as that assigned to the components of suffering, and in the last example the grade in domain 5 is greater than any of the individual grades because compromise in two areas magnifies distress.

1. Operant conditioning with positive reinforcement using animals accustomed to the experimental environment and apparatus.

Domain

- | | |
|----------------------------------|---------|
| 1. Fluid/food intake unaffected | Grade O |
| 2. Thermoneutral environment | Grade O |
| 3. Healthy, uninjured animals | Grade O |
| 4. Minor behavioural restriction | Grade A |
| 5. No suffering | Grade O |

Overall grade: A

2. Studies of limited gut resection (removal) and its consequences.

- | | |
|--|---------|
| 1. Fluid/food intake affected slightly | Grade A |
| 2. Thermoneutral environment | Grade O |
| 3. Anaesthesia plus surgery with effective analgesia | Grade B |
| 4. Minor behavioural restriction (indoor individual pen) | Grade A |
| 5. Moderate pain/distress (mainly with surgery) | Grade B |

Overall grade: B

3. Blood sampling of recently confined and untamed free-range domesticated animals with strong flight responses.

- | | |
|---|---------|
| 1. Fluid/food intake affected slightly (reduced for first 48 h) | Grade A |
| 2. Thermoneutral environment | Grade O |
| 3. Simple venipuncture of healthy uninjured animals | Grade A |
| 4. Mild behavioural restriction (handling, large indoor pen) | Grade A |
| 5. Marked fear/distress (mainly from handling/restraint) | Grade C |

Overall grade: C

4. Studies of usually fatal viral diarrhoea in hand reared newborn animals.

- | | |
|---|---------|
| 1. Fluid/food intake moderately affected | Grade B |
| 2. Thermoneutral environment | Grade O |
| 3. Extreme debility or functional compromise | Grade X |
| 4. Minor behavioural restriction | Grade A |
| 5. Severe pain/distress (mainly from gut effects) | Grade X |

Overall grade: X

5. Studies of underfed animals exposed to severe cold for a short period (24 h).

- | | |
|--|---------|
| 1. Food intake restricted to cause weight loss of 20% | Grade B |
| 2. Cold challenge at the limit of animal's adaptive response | Grade B |
| 3. Mild functional impairment | Grade A |

- | | |
|---|---------|
| 4. Mild behavioural restriction (indoor individual pen) | Grade A |
| 5. Marked overall distress (from underfeeding and cold) | Grade C |

Overall grade: C

Quantification

In all five domains we have attempted to distinguish between the different grades using features which are measureable. At worst the distinctions will be as crude as 'absent' or 'present', or 'small' or 'big', but even imprecise distinctions are a form of quantification. In such cases there would be a clear need to seek better indices. At best, and mostly, measureable parameters with numerical scales are available for use (Mellor, 1992), although particular care is required when attempting to quantify the components of suffering (e.g. Chapman, 1992; Gebhardt, 1992; Manteca and Deag, 1993; Mason and Mendl, 1993; Wemelsfelder, 1993). Whatever scales are adopted, there will be a clear need to continually review their usefulness in terms of the information they provide, their ability to discriminate between the different levels of severity and their practicality. Later papers at this conference contribute to the subject of measureable indices of welfare status.

Difficulties in Grading Severity

Great care must be taken to consider *all* possible outcomes of a proposed experiment, in the long term as well as the short term. Assigning a single impact rating for a group of animals involved in a given experiment ignores the possibility of individual variation in animal responses - for instance, some individuals may suffer heat loss more than others, or socially dominant animals may consume a disproportionately large amount of the food offered to a group. Other difficulties may also arise. In field observations of animal behaviour, Cuthill (1991) notes the need to consider the possible effects of a field experiment on species other than the target animal; he also points out that even apparently benign food supplementation can have strongly deleterious consequences. Most problems of this nature can be avoided by a good understanding of the interactions between the animals involved and their biological and physical environments. More difficult is the problem of predicting the outcome of highly dynamic situations such as excessive inter- or intra-specific aggression - the need for such experiments requires very careful examination and, if permitted, they should be given a high grading on the basis of the worst-case-scenario.

COST-BENEFIT ANALYSIS

In order to conduct a cost-benefit analysis for an experiment, each grade of the severity scale must represent a defined level of ethical cost *and* a required level of justification. Without appropriate justification a proposed experiment would not be approved by an institutional Animal Ethics Committee and therefore could not legally be carried out. As the ethical cost rises, clearly so also must the stringency and strength of justifications for carrying out the proposed research (Figure 6). Grading the extent of compromise in all five domains is important because it is only if we have comprehensively evaluated the full extent of *all* proposed intrusions that we can assess fully the acceptability of a justification for a proposed experiment.

The ethical cost and the required justification for each grade on the severity scale are outlined in Table 3. The following points should be noted.

1. The justification for O graded experiments would not need to be in terms of benefits to humans, other animals or both.
2. Both indirect and direct benefits would be acceptable for justifying A graded experiments, whereas usually only direct benefits could be used to justify experiments graded B, C or X.

The question of the meaning of the terms 'indirect benefits' and 'direct benefits' has been left open purposely. These terms have been introduced to highlight the

need for the experimenter to consider as part of the justification whether the contribution the proposed work is likely to make will be *fundamental* (Will the work simply increase understanding?), *strategic* (Is it likely to help solve a problem in the medium to long term?) or *applied* (Will the results contribute immediately to solving a problem?).

3. Proposed experiments in all the grades A to X would be disallowed if adequate justification were not provided.
4. Grade X is included to make explicit the upper limits of acceptable experiments, where the most exceptional justification would be required for such experiments to proceed.
5. The question of what the terms 'justification', 'good justification', 'strong justification' and 'most exceptional justification' mean has also been left open purposely. The researcher will need to assign each proposed experiment to one of these categories and test the specific justification for it with colleagues and the institutional Animal Ethics Committee. In that way a consensus will develop. We may expect that consensus to change with time as knowledge and societal attitudes advance.

The interdependence of the assessed impact on the animals of a proposed study and the justification for the proposal when making cost-benefit decisions is plain (see also: Bateson, 1986; Porter, 1992). Even under the best circumstances cost-benefit decisions can be difficult to make. Clearly, when we approve any experiment graded higher than O we decide that the reasons for the study outweigh the graded cost to the animals. Thus the interests of the animals which are to be used are subordinated to our purposes in using them. Therein lies a danger. Even when the present system for grading welfare compromise is used to make such decisions, we must remain aware that the necessary and repeated subordination of the experimental animals' interests to our own purposes in the research context could *desensitise* us to the true cost to those animals. That would be the opposite outcome to the one we seek in proposing the present system. One means of avoiding that desensitisation would be for us (experimenter and Committee) to reflect on the futility of each proposed study and the associated needless suffering (as graded) that would be caused if the desired animal usage, when carried out, were to fail. That process would have the further advantage of re-emphasising that the experimental design of each proposal *must* be capable of answering the questions the proposal is expected to address.

RESEARCHER'S RESPONSIBILITIES

Researchers are ethically responsible as individuals for the experiments they conduct on animals. Assessing thoroughly the intrusiveness or severity of any proposed experiment is an important step in exercising that responsibility. Such an assessment is not a trivial matter to be dealt with casually as an administrative obstacle that must be overcome before the proposed work can proceed. Nor can this responsibility be delegated to institutional Animal Ethics Committees. Those committees may provide guidance on the acceptability of severity gradings and the associated justifications for the work, and they do regulate the experimental activities according to the law, but the ethical responsibility for each experiment remains primarily with the researcher. Accordingly the onus is on the researcher to justify every aspect of a proposed experiment, including its scientific quality and significance.

Researchers are ethically bound to minimise the severity of every experiment. Once it has been decided that animals do need to be used (i.e. replacement is not appropriate) and the general features of the proposed experiments have been determined, active steps must then be taken to refine or modify the protocols to try to reduce their anticipated impact. Although refinement should be attempted with all experiments graded more severely than O, there is a particular obligation to do so with experiments graded C or X. For instance, with X graded experiments where the predicted end point for conscious animals is extreme debility/incapacity or an unpleasant death, attempts must be made to discover and use more humane end points. Indeed, it can be argued that institutional Animal Ethics Committees

should not approve such experiments, however exceptional their justification, unless a specific part of the protocol is designed to devise a more humane end point. The particular purpose of such a stricture would be to make it mandatory to try to reduce the severity rating of subsequent similar work. Early euthanasia or the use of sedatives, for example, might reduce a severity grade for such work from X to C or B.

Researchers' responsibilities continue throughout the period of animal use and beyond. During experiments, throughout the period from acquisition to disposal of the animals, the researcher has total responsibility for all aspects of the animals' care, maintenance and use, whatever support may be provided by institutional or other services. The best available methods at the highest standards of use must be employed. Regular monitoring of welfare status is also imperative. Furthermore, there is an obligation at the end of an experiment to use the experience gained to reassess all aspects of the work in order to (1) seek avenues to reduce the severity of the procedures used and, if appropriate, (2) to regrade the experiment up or down the severity scale. Any such regrading and the reasons for it should be reported to the institutional Animal Ethics Committee to assist its future deliberations. We regard feedback to the Animal Ethics Committee as critical to the process of building up a pool of experience for the Committee (and others) to draw upon (Reid and Mellor, 1993).

Researchers are responsible for providing training and advice to all novices, including inexperienced scientists, technicians and animal care personnel. Experienced researchers, by their behaviour, must set examples of responsible action and respect for the animals. In addition, they should establish clearly defined lines of communication and modes of contact for dealing with untoward events.

HUMAN-ANIMAL DISCONTINUITIES

There are two important limitations to the system set out here which are common to all systems of grading or assessment so far proposed. They arise because of the communication and experiential discontinuities between humans and other animals which accompany all human-animal interactions.

- (1) Humankind is at present unable to communicate directly with other animals or to understand fully how their sensory world is affected by what we do around them, or to them, and how they interpret and react to these intrusions.
- (2) We necessarily use our human experience to anticipate the impact of our intrusions on other animals, and describe that impact in terms which are meaningful to us but which may have poor relevance to the animals' actual perceptions, sensations or concerns.

We acknowledge these limitations here to highlight the difficulty of understanding fully the life experiences (good and bad) of other animals. However, these obstacles should not deter us from our present purpose because they attend all of our interactions with other animals and not simply those in the research environment. In all spheres we can only continue to interact with other animals using the best devices available, however flawed they may be.

ANIMAL WELFARE/WELL-BEING IN THE RESEARCH ENVIRONMENT

Good welfare/well-being is the state of being manifest in an animal when its nutritional, environmental, health, behavioural and mental needs are met.

It is imperative that we strive for the highest standards of animal welfare in the research environment, not only because of our ethical responsibility to the animals we use, but also because of our responsibility to the community in which we work. We are accountable to that community and we must be seen by that community to behave in a caring and disciplined manner. If we are to continue in our researches, we need to retain its respect.

An important part of retaining that respect in to be seen to be operating transparent systems honestly and openly. Nowhere is this more important than in our assessments of the impact of our experimental procedures on our experimental animals, our justifications for carrying out those procedures and the cost-benefit decisions we make. It is awareness of this need which has motivated this paper.

In the authors' view assessment of the impact of the experimental procedures in the keystone. The efficiency and accuracy of those assessments should be improved by use of the system based on the five domains of welfare/well-being compromise described here. Although at present the indices used in the five domains may be imprecise or precise, qualitative or quantitative, controversial or established, they do provide the best means we have at hand to grade the severity of compromise likely to be or actually caused by an experiment. That severity sets the strength and stringency of the justification which must be advanced before an experiment should proceed.

It is the research worker who plays the leading role in the process, who conceives and designs the proposed experiment, assesses its negative impact on the subjects, looks for ways to reduce that impact, assembles the justification, attempts the first cost-benefit analysis and then takes the case to the institutional Animal Ethics Committee. The conscientiousness and comprehensiveness of the assessments of compromise and the actions taken to minimise it are measures of the researcher's acceptance of ethical responsibility for all features of each experiment which affect the animals adversely.

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Table 1: The Five Freedoms (FAWC, 1992)

Freedom	How promoted
1. Freedom from thirst, hunger and malnutrition.	By ready access to fresh water and a diet to maintain full health and vigour.
2. Freedom from discomfort.	By providing an appropriate environment, including shelter and a comfortable resting area.
3. Freedom from pain, injury and disease.	By prevention or rapid diagnosis and treatment.
4. Freedom to express normal behaviour.	By providing sufficient space, proper facilities and company of the animal's own kind.
5. Freedom from fear and distress.	By ensuring conditions which avoid mental suffering.

Table 2: Descriptions and examples of grades on the severity scale for the five domains of potential welfare compromise.

Domain 1:	<i>Thirst/hunger/malnutrition</i>
Grade O	<p><i>Water/fluid is available in quantities which satisfy thirst.</i></p> <p><i>Food of appropriate types and compositions for the species is made available in amounts which meet body maintenance requirements plus any additional demands imposed by factors such as pregnancy, lactation, growth, exercise, thermal challenge or recuperation from illness or injury.</i></p> <p>For instance: animals kept outdoors eating their usual food in appropriate amounts; grazing trials on treated pastures; offering supplements to naturally available food; provision of complete, balanced rations to meet all nutritional requirements of animals maintained indoors.</p>
Grade A	<p><i>Water/fluid or food restrictions or excesses which cause minor, readily reversed effects on physiological state, body condition or performance.</i></p> <p>For instance: water priming for kidney function tests; short-term overall food intake restrictions or excesses which are within usual tolerance levels for the species; short-term changes in dietary composition which cause no clinical symptoms of deficiency or toxicity, but which would cause such symptoms in the longer term.</p>
Grade B	<p><i>Water/fluid or food restrictions or excesses which cause serious short-term or moderate long-term effects on physiological state, body condition or performance, but such effects remain within the capacity of the body to respond to nutritional variations and allow spontaneous recovery after the restoration of a good quality diet at the required intakes.</i></p> <p>For instance: simulation of usual overall intake restrictions often experienced by pregnant/lactating ruminants during cold winters or drought; dietary induction of milk fever in cattle; induction of mild deficiency or toxicity symptoms by feeding diets containing inadequate or excessive amounts of essential nutrients.</p>
Grade C	<p><i>Water/fluid or food restrictions or excesses which lead to levels of debility where euthanasia would be used to avoid an inevitable further decline because therapy would either be ineffective or too protracted.</i></p> <p>For instance: dietary induction of advanced pregnancy toxemia in sheep or of ketosis in dairy cattle; dietary induction of advanced symptoms of nutrient deficiency or excess; severe deleterious effects of dietary toxins.</p>
Grade X	<p><i>Water/fluid or food restrictions or excesses where the predicted end point is death.</i></p> <p>For instance: experiments which cause animals to die from dehydration or starvation, nutrient excess or deficiency, or poisoning by toxins in the diet.</p>

Domain 2: Environmental challenge

Grade O *Experiments involving outdoor or indoor environmental conditions which elicit body responses that remain inside the animals' capacity to react to external stimuli without recourse to adaptive physiological changes.*

For instance: ambient conditions which are within the thermoneutral range; reduced barometric pressures which do not cause increases in red blood cell production.

Grade A *Experiments which cause body responses that remain within the homeostatic capacity of the animals to react but involve adaptive physiological responses.*

For instance: exposure to levels of cold or heat which are outside the thermoneutral range, or barometric pressures which increase red blood cell production, but which remain within the capacity of the animals to adapt and do not lead to debility in the long term.

Grade B *Experiments which represent marked short-term or moderate long-term environmental challenges that elicit body responses beyond the physiological adaptive capacity of the animals, but where the untoward effects are readily reversed by restoration of benign conditions with or without additional therapeutic intervention.*

For instance: short-term exposure to severe cold or heat which would lead to collapse if prolonged.

Grade C *Experiments which represent extreme environmental challenges that lead to serious physiological compromise, where euthanasia would be used to prevent an inevitable further decline or because therapeutic procedures would be ineffective or too protracted.*

For instance: prolonged exposure to severe cold which would lead to failure of thermoregulation and collapse, but the exposure is terminated just before those outcomes.

Grade X *Environmental experiments which cause protracted extreme physiological compromise or where the end point is death.*

For instance: exposure to lethal extremes of cold, heat or barometric pressure.

Domain 3: Disease/injury/functional impairment

Grade O *Experiments with healthy animals which do not cause or involve disease, injury or functional impairment.*

For instance: studies of healthy uninjured animals which are kept in physical conditions which do not themselves lead to injuries such as lameness or compression sores; studies to establish normal characteristics of healthy animals.

Grade A *Experiments which cause body responses that remain within the homeostatic capacity of the animals to react with no or only minor debility or incapacity.*

For instance: studies of vaccines using killed pathogens; tuberculosis tests; induction of mild fever without other debilitating effects; induction of subclinical parasitism; healing of minor superficial incisions, cuts or wounds; minor surgical and/or pharmacological modification of homeostatic capacity (e.g. creation of non-obstructive gut fistulae; splenectomy; endocrine gland removal with complete hormone replacement therapy); physical conditions which cause minor and transient lameness, compression sores or abrasions.

Grade B *Experiments which cause marked short-term or moderate long-term functional changes associated with moderate debility or incapacity, but from which complete recovery occurs spontaneously or can be readily effected therapeutically.*

For instance: studies of live vaccines; induction of clinical parasitism; induction of mild reversible infectious diarrhoea; moderate surgical and/or pharmacological modification to homeostatic capacity (e.g. limited gut resection; endocrine gland removal with delayed or incomplete hormone replacement therapy); physical conditions which cause minor chronic lameness or other injuries.

Grade C *Experiments which cause marked debility or incapacity and serious physiological compromise, where euthanasia would be used to prevent an inevitable further decline because therapeutic procedures would be ineffective or too protracted. Experiments which cause death unpredictably in a small proportion of animals because a rapid deterioration in their state can occur with little or no warning.*

For instance: studies of severe facial eczema; induction of severe diarrhoea or severe infectious pneumonia; protracted or irreversible pharmacological modification of homeostatic capacity (e.g. chemical induction of diabetes mellitus without replacement therapy); marked surgical modification of homeostatic capacity (e.g. extensive gut resection; cutting of sensory or motor nerves serving large areas of the body; precise lesioning of limited areas of the brain but with intervention before collapse); physical conditions which cause moderate chronic lameness or other injuries.

Grade X *Experiments in conscious animals which cause extreme debility or incapacity or where the predicted end point is an unpleasant death.*

For instance: studies of biological or other methods for killing pest animals; toxicity testing using the traditional LD 50 test; evaluation of vaccines where death is the measure of failure to protect; studies of the pathogenesis of fatal diseases caused by infectious or toxic agents; studies of recovery from third degree burns or serious traumatic injuries.

Domain 4: Behavioural/interactive restriction

Grade O *Experiments which do not interfere with the behavioural needs of individuals or groups of animals (an animal's behavioural needs being those activities which when thwarted produce untoward physiological or psychological effects).*

For instance: studies of wild or undomesticated animals in their natural habitats; field studies of domesticated animals.

Grade A *Experiments which cause minor interference with the behavioural needs of individuals or groups of animals.*

For instance: mild and short-term physical restraint; keeping free-range domesticated animals in a yard; operant conditioning with positive reinforcement in barren laboratory environments; benign preference tests in unnatural surroundings.

Grade B *Experiments which cause marked short-term or moderate long-term interference with the behavioural needs of individuals or groups of animals resulting in untoward physiological or psychological effects which are readily reversed by the restoration of benign conditions with or without additional therapeutic intervention.*

For instance: medium-term restrictions of instinctive behaviour; medium-term holding of ruminants in a metabolism crate; long-term restraint leading to the development of reversible stereotypies; changing social group composition.

Grade C *Experiments which markedly interfere with the behavioural needs of individuals or groups of animals leading to severe physiological or psychological compromise requiring restoration of benign conditions, with or without additional therapeutic intervention, or the use of euthanasia to limit the magnitude or duration, or both, of the imposed compromise.*

For instance: application of marked and repeated noxious stimuli from which escape is impossible; prolonged periods (several hours or more) of close physical restraint; induction of aggressive behaviour leading to self-mutilation or excessive intraspecific aggression; marked alterations to the perceptual or motor functions of animals to test consequent behaviour.

Grade X *Experiments which cause severe interference with the behavioural needs of individuals or groups of animals leading to psychotic-like behaviour or to agonistic interactions that result in severe injury or death.*

Such states might manifest as profound withdrawal, agitation, self-mutilation or aggression towards others caused by social deprivation, prolonged exposure to an impoverished environment, excessive physical confinement or restraint, over-crowding, exposure to severe noxious stimuli, maternal deprivation with substitution of punitive surrogates and the like.

Domain 5: Anxiety/fear/pain/distress*

Grade O *Experiments which do not cause anxiety, fear, pain or distress such as non-invasive observation of animals in unchallenging circumstances.*

For instance: field observations of grazing behaviour on farms, or benign handling of tamed and trained animals which are familiar with all personnel and procedures and with the place where the procedures are conducted.

Grade A *Experiments which cause minor discomfort or low-level anxiety or apprehension for short periods.*

For instance: experiments on completely anaesthetised animals which do not regain consciousness; standard methods of euthanasia that rapidly induce unconsciousness, (e.g. anaesthetic overdose); simple venipuncture or venisection; injection of non-toxic substances; skin tests which cause low-level irritation without ulceration; feeding trained animals by orogastric tube; movement of free-range domesticated animals to unfamiliar housing.

Grade B *Experiments which cause moderate anxiety, fear, pain, or distress for short periods or minor discomfort or distress for long periods.*

For instance: recovery from major surgeries like thoracotomy, orthopaedic procedures, hysterectomy or gall bladder removal, with effective use of analgesics; surgical procedures on conscious animals but with the use of local anaesthesia and systemic analgesic; movement of excitable free-range domesticated livestock to unfamiliar housing.

Grade C *Experiments which cause marked anxiety, fear, pain or distress where any suffering caused is ended by euthanasia or by therapeutic or other interventions before it becomes excessive or where the suffering is short-lived and complete recovery can occur. Experiments which cause moderate anxiety, fear, pain or distress for long periods.*

For instance: recovery from major surgery without the use of analgesics; marked social or environmental deprivation; capture, handling, restraint or housing, without the use of tranquilisers, of wild or semi-domesticated animals that exhibit marked flight responses.

Grade X *Experiments which cause severe, inescapable or unrelieved anxiety, fear, pain or distress where the intensity or duration, or both, of the induced suffering are at or beyond the limits of reasonable endurance.*

For instance: conducting major surgeries without the use of anaesthesia (e.g. where the animal is immobilised physically or with muscle relaxants); testing the efficacy of analgesics in animals with induced severe pain.

*Outcomes of experiments which focus on the first four domains will often contribute to the grading in the fifth domain (see Figure 5).

Table 3: Level of ethical cost and required justification for experiments at each grade of the severity scale.

Grade O`	Ethical cost - nil or virtually nil. Such experiments would not usually require justificaion in terms of expected indirect or direct benefits to humans, other animals or both.
Grade A	Ethical cost - low. Such experiments would require justification regarding the expected indirect or direct benefits to humans, other animals or both.
Grade B	Ethical cost - moderate. Such experiments would require good justification regarding the expected direct benefits to humans, other animals or both.
Grade C	Ethical cost - high. Such experiments would require strong justification regarding the expected direct benefits to humans, other animals or both.
Grade X	Ethical cost - very high. Such experiments would require the most exceptional justification and would be permitted only very rarely.

- Figure 1. The three dimensions of science.
- Figure 2. (a) The health-illness continuum.
(b) The health-illness continuum with a health focus,
(c) The health illness continuum with an illness focus.
- Figure 3. Different degrees of health-illness at different positions on the continuum.
- Figure 4. (a) The welfare-suffering continuum.
(b) The welfare-suffering continuum with a welfare focus.
(c) Different degrees of welfare-suffering at different positions on the continuum.
- Figure 5. The five domains of potential welfare compromise. Compromise in domains 1-4 will usually be registered in welfare terms in domain 5 which represents the components of suffering.
- Figure 6. Schematic presentation of cost benefit decisions which must balance the grades of anticipated welfare compromise (O, A, B, C, X) and the necessary strength of justification required (see Table 3) before an experiment could proceed.